IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Jorg J. Goronzy et al.	Art Unit	: 1648
Serial No.	: 09/723,000	Examiner	: Stacy Brown Chen
Filed	: November 27, 2000		
Title	: METHODS AND MATERIALS FOR EVALUATING RHEUMATOID ARTHRITIS		

MAIL STOP ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR §1.705(B)

Applicants hereby petition for reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent application. Attached herewith is a copy of the Notice of Allowance including a Determination of Patent Term Adjustment under 35 U.S.C. §154(b), mailed October 6, 2004, for the above-referenced application. The Notice of Allowance states that the Patent Term Adjustment at allowance is 0 days. Correction of the Patent Term Adjustment calculation to increase PTO Delay from 156 days to 477 days, decrease Applicant Delay from 318 days to 127 days, and to increase Total PTA from 0 days to 350 days, is respectfully requested.

01/07/2005 HGUTEMA2 00000078 09723000
01 FC:1463 200.00 OP

01/13/2005 HGUTEMA2 00000005 09723000
03 FC:1455 200.00 OP

CERTIFICATE OF MAILING BY EXPRESS MAIL

Express Mail Label No. EV467325075US

January 5, 2005
Date of Deposit

I. REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

A review of the Patent Term Adjustment History in the PAIR/PALM system shows that the United States Patent and Trademark Office (PTO) calculated the Patent Term Adjustment (PTA) as follows:

1) The PTO mailed a "Miscellaneous Communication to Applicant" on July 2, 2002, and accorded a PTO Delay of 156 days. Applicants respectfully submit that the PTO's calculation of PTO Delay contains an error and that the correct PTO Delay associated with mailing this action is 0 days.

2) Applicants submitted a response to the above-referenced communication on July 15, 2002. The PAIR/PALM system indicates entry of a Preliminary Amendment on July 22, 2002, but does not indicate entry of the response to the communication until April 11, 2003, thereby according an Applicant Delay of 191 days. Applicants respectfully submit that the PTO's calculation of Applicant Delay contains an error and that the correct Applicant Delay associated with this response is 0 days.

3) The PTO mailed a non-final Office Action on May 19, 2003. No PTO Delay was accorded with regard to the mailing of this action. Applicants respectfully submit that the PTO's calculation of PTO Delay contains an error and that the correct PTO Delay is 477 days.

4) Applicants submitted a response to the May 19, 2003 Office Action on September 19, 2003. The PAIR/PALM system indicates entry of the response on September 22, 2003. An Applicant Delay of 34 days was accorded. Applicants concur with this patent term adjustment calculation.

5) The PTO mailed a final rejection on November 17, 2003, to which Applicants responded on May 20, 2004, by way of a Notice of Appeal. An Applicant Delay of 93 days was accorded. Applicants concur with this patent term adjustment calculation.

6) The PTO calculates a total PTO Delay of 156 days and a total Applicant Delay of 318 days, for a total (net) PTA of 0 days. Applicants respectfully submit that the

PTO's calculation of Applicant Delay contains an error and that the correct total PTO Delay is 477 days; the correct total Applicant Delay is 127 days; thus yielding a total PTA of 350 days.

II. CALCULATION OF APPLICANT DELAY

A. Applicants' July 22, 2002 Response to the Communication of July 2, 2002, was incorrectly entered into PAIR/PALM on April 11, 2003

On July 2, 2002, the PTO mailed a "Miscellaneous Communication" to Applicants. In response to the communication, Applicants mailed a Preliminary Amendment and a Response to Notice to Comply on July 15, 2002, including a certificate of mailing under 37 CFR §1.8(a) (copy enclosed). The items were received by the PTO on July 22, 2002, as evidenced by the PTO date-stamped return receipt postcard (copy enclosed); however, only the preliminary amendment was entered into the PAIR/PALM system on that date. The Response to Notice to Comply was not entered until April 11, 2003. As both items were mailed together in the same package, and receipt of both items is indicated on the date-stamped postcard, both items should be entered on the same date in PAIR/PALM.

No Applicant Delay should be calculated in association with this response, as Applicants' complete and timely response was received by the PTO on July 22, 2002, well within the three-month period for response ending October 2, 2002.

III. CALCULATION OF PTO DELAY

A. PTO Delay for a Delayed First Office Action Should Continue to Calculate Until May 19, 2003

The PAIR/PALM screen indicates that the patent term adjustment calculation of PTO Delay for a delayed 14-month first Office Action is calculated until July 2, 2002, when the PTO mailed a "Miscellaneous Communication" to Applicants. Applicants submit that the communication mailed July 2, 2002, is not a first action on the merits as provided in 35 U.S.C. §132, and thus does not meet the requirement of 35 U.S.C. §154(b)(1)(A)(i) of the

PTO to mail at least one of either a notification under 35 U.S.C. §132 or a notice of allowance for patent term adjustment calculation purposes in 37 CFR §1.703(a)(1).

The communication mailed July 2, 2002 (copy enclosed), is, in essence, a notice to comply with sequence requirements and is nearly identical to the action mailed April 4, 2002 (copy enclosed), which was entered into PAIR/PALM as, "Mail Letter Requiring CRF (Unreadable, Non-Compliant, Not Submitted)," and which did not stop the 14-month first action clock. Had the action of July 2, 2002, been entered, appropriately, as, "Mail Letter Requiring CRF," the PTO Delay calculation would have continued until the true first action on the merits of the case, a non-final rejection mailed May 19, 2003. With this action as the first action under 35 U.S.C. §132, the calculated PTO delay under 37 CFR §1.703(a)(1) would be 477 days, instead of the currently calculated 156 days.

B. In the Unlikely Event That the July 2, 2002 Communication is Correctly Identified as an Action Under 35 U.S.C. §132, PTO Had a Duty to Respond to Applicants' Reply of July 22, 2002, Within 4 Months

Applicants responded to the communication mailed July 2, 2002, on July 15, 2002, with receipt documented by the PTO date-stamped return receipt postcard on July 22, 2002. Under 35 U.S.C. §154(b)(1)(A)(ii), the PTO must reply to this response within four months after the date on which the reply was filed. As the PTO received Applicants' response on July 22, 2002, the PTO should have mailed a response by November 22, 2002. The next action by the PTO was not mailed until May 19, 2003. No PTO Delay is currently calculated for this action. Under 37 CFR §1.703(a)(2), the calculated PTO Delay for this action should be 178 days. Under this scenario, the total PTO Delay would be 334 days, yielding a total PTA of 207 days. Applicants note, however, that the July 2, 2002 communication should not be considered a first action. Thus, as explained above, the total PTO Delay should be calculated as 477 days, yielding a total PTA of 350 days.

IV. DOCUMENTS ENCLOSED

A copy of each of the following documents is provided herein:

1) Notice of Allowance mailed October 6, 2004;

2) Preliminary Amendment and Response to Notice to Comply mailed July 15, 2002, and PTO date-stamped return receipt postcard indicating receipt date of July 22, 2002;

3) "Miscellaneous Communication" mailed July 2, 2002; and,

4) "Letter Requiring CRF" mailed April 4, 2002.

V. REMARKS

In consideration of the events described above, Applicants believe the Total PTA calculation of 0 days is incorrect. Applicants respectfully request recalculation of the patent term adjustment in the following manner:

1) Total Applicant Delay should be calculated as 127 days (34 days for September 22, 2003 delayed response to non-final action of May 19, 2003; 93 days for May 20, 2004 delayed response (Notice of Appeal) to final rejection mailed November 17, 2003); and,

2) Total PTO Delay should be calculated as 477 days (for a delayed first non-final Office Action).

Applicants therefore respectfully request the removal of 191 days of Applicant Delay, thus decreasing Applicant Delay from 318 days to 127 days; the addition of 321 days of PTO Delay for a total of 477 days; and a resulting increase of the Total PTA from 0 days to 350 days.

Applicants also kindly request correction of the file history in the PAIR/PALM system to indicate the correct date of receipt of Applicants' response mailed July 15, 2002, and received by the PTO on July 22, 2002.

Enclosed is a check for the fee of $200 required under 37 CFR §1.18(e). Please apply any other required charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: January 5, 2005

J. Patrick Finn III, Ph.D.
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60268050.doc

MSE
JXF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26191 7590 10/06/2004

FISH & RICHARDSON P.C.
3300 DAIN RAUSCHER PLAZA
60 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/06/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,000	11/27/2000	Jorg J. Goronzy	07039-170002	4888

TITLE OF INVENTION: METHODS AND MATERIALS FOR EVALUATING RHEUMATOID ARTHRITIS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$685	$0	$685	01/06/2005

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 09/04) Approved for use through 04/30/2007.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (703) 746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26191 7590 10/06/2004

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3300 DAIN RAUSCHER PLAZA
60 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (703) 746-4000, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,000	11/27/2000	Jorg J. Goronzy	07039-170002	4888

TITLE OF INVENTION: METHODS AND MATERIALS FOR EVALUATING RHEUMATOID ARTHRITIS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$685	$0	$685	01/06/2005

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHEN, STACY BROWN	1648	435-007100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are enclosed:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.
NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,000	11/27/2000	Jorg J. Goronzy	07039-170002	4888

26191 7590 10/06/2004

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MINNEAPOLIS, MN 55402

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 10/06/2004

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Docketed By Practice Systems
Action Code: Issue Fee/PTA Petition
Base Date: 10-6-04
Due Date: 12-6-04
Deadline: 1-6-05
Initials: JAN
Record:

Docketed By Practice Systems
Action Code: FILECON-DV
Base Date: 10-6-04
Due Date: 12-6-04
Deadline: 1-6-05
Initials: JAN
Record:

Docketed by Billing
Due Date: 12/6/05
Deadline: 1/6/05
Initials: ko for DAS

Docketed by Billing
Due Date: 12/6/04
Deadline: 1/6/05
Initials: ko for DAS

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,000	11/27/2000	Jorg J. Goronzy	07039-170002	4888

26191 7590 10/06/2004

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MINNEAPOLIS, MN 55402

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/06/2004

Notice of Fee Increase on October 1, 2004

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after October 1, 2004, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" because some fees will increase effective October 1, 2004. See Revision of Patent Fees for Fiscal Year 2005; Final Rule, 69 Fed. Reg. 52604, 52606 (May 10, 2004).

The current fee schedule is accessible from WEB site (http://www.uspto.gov/main/howtofees.htm).

If the fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due" but not the correct amount in view of the fee increase, a "Notice of Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice of Pay Balance of Issue Fee," if the response to the Notice of Allowance is to be filed on or after October 1, 2004 (or mailed with a certificate of mailing on or after October 1, 2004), the issue fee paid should be the fee that is required at the time the fee is paid. See Manual of Patent Examining Procedure (MPEP), Section 1306 (Eighth Edition, Rev. 2, May 2004). If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously-paid issue fee should be paid. See MPEP Section 1308.01.

Effective October 1, 2004, 37 CFR 1.18 is amended by revising paragraphs (a) through (c) to read as set forth below.

Section 1.18 Patent post allowance (including issue) fees.

(a) Issue fee for issuing each original or reissue patent, except a design or plant patent:
- By a small entity (Sec. 1.27(a)) $685.00
- By other than a small entity $1,370.00

(b) Issue fee for issuing a design patent:
- By a small entity (Sec. 1.27(a)) $245.00
- By other than a small entity $490.00

(c) Issue fee for issuing a plant patent:
- By a small entity (Sec. 1.27(a)) $330.00
- By other than a small entity $660.00

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Notice of Allowability	Application No.	Applicant(s)	
	09/723,000	GORONZY ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *July 23, 2004*.

2. ☒ The allowed claim(s) is/are *48-56 and 60*.

3. ☒ The drawings filed on *09 September 2003* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ Including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Patrick Finn on September 29, 2004.

The application has been amended as follows:

IN THE CLAIMS:

Claims 57, 61 and 62 have been cancelled.

Claim 48 has been amended as follows:

48. A method for determining the predisposition of a rheumatoid arthritis patient to develop severe disease, said method comprising:

a) comparing the frequency of $CD4^{+}/CD28^{null}$ cells in said patient to a reference frequency to obtain information about said rheumatoid arthritis condition, and

b) determining if said patient is predisposed to develop severe disease based on said information and the presence or absence of an HLA-DRB1 allele in said patient, wherein said HLA-DRB1 allele is an HLA-DRB1 *0401 allele, an HLA-DRB1 *0404 allele, an HLA-DRB1 *0405 allele, or an HLA-DRB1 *0408 allele;

wherein said severe disease comprises subcutaneous nodule formation or extra-articular involvement.

Claim 60 has been amended as follows:

60. A method for determining the predisposition of a rheumatoid arthritis patient to develop severe disease, said method comprising:

a) determining the frequency of $CD4^{+}/CD28^{null}$ cells in said patient,

b) determining the presence or absence of an HLA-DRB1 allele in said patient, wherein said HLA-DRB1 allele is an HLA-DRB1 *0401 allele, an HLA-DRB1 *0404 allele, an HLA-DRB1 *0405 allele, or an HLA-DRB1 *0408 allele,

c) comparing said frequency of $CD4^{+}/CD28^{null}$ cells to a reference frequency to obtain information about said rheumatoid arthritis condition, and

d) determining if said patient is predisposed to develop severe disease based on said information and said presence or absence of said HLA-DRB1 allele;

wherein said severe disease comprises subcutaneous nodule formation or extra-articular involvement.

Examiner's Comments

2. Claims 57, 61 and 62 were cancelled. Applicant indicated that the cancellation of claims is made without prejudice. The amendments to claims 48 and 60 were made in order to clarify the meaning of "severe disease". "Severe disease" is a severe form of rheumatoid arthritis, marked by subcutaneous nodule formation and/or extra-articular involvement (specification, page 3, lines 2-4).

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance:

Applicant's appeal brief, filed July 23, 2004 is acknowledged. The arguments contained in the brief, regarding the rejection of claims 48-57 (claim 57 is now cancelled) and 60 under 35 U.S.C. 103(a) as obvious over Goronzy *et al.* (*J. Clin. Investigation*, 1994, 94:2068-2076) in view of Abril *et al.* (*Arthritis Rheum.* 1998, 40:762), had been presented in previous responses. However, upon further consideration, the arguments were found persuasive. There is no motivation in the art of record to combine the teachings of Goronzy *et al.* with Abril *et al.* As evidence that there is no motivation to combine the two references, Applicant points to the Chapman *et al.* reference (*J. Immunol.* 1996, 157:4771-4780) which discloses that frequency of $CD4^{+}/CD28^{null}$ cells and the presence/absence of HLA-DRB alleles are associated. Applicant argues that one would not have been motivated to combine Goronzy *et al.* with Abril *et al.*, which measure both factors (frequency of $CD4^{+}/CD28^{null}$ cells and the presence/absence of HLA-DRB alleles), because Chapman *et al.* teaches that the presence of one of the factors necessarily leads to the other, and therefore the measurement of both factors is not required. Lacking motivation to combine the two reference's teachings, one would not have arrived at the invention claimed in claims 48-57 (claim 57 is now cancelled) and 60.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

4. Claims 48-56 and 60 are allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
September 30, 2004

JAMES HOUSEL 10/1/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

09/723,000 Pending after FE w/ Examiner's Amdt. 9/30/2004 SBC

48. A method for determining the predisposition of a rheumatoid arthritis patient to develop severe disease, said method comprising:

a) comparing the frequency of $CD4^+/CD28^{null}$ cells in said patient to a reference frequency to obtain information about said rheumatoid arthritis condition, and

b) determining if said patient is predisposed to develop severe disease based on said information and the presence or absence of an HLA-DRB1 allele in said patient, wherein said HLA-DRB1 allele is an HLA-DRB1 *0401 allele, an HLA-DRB1 *0404 allele, an HLA-DRB1 *0405 allele, or an HLA-DRB1 *0408 allele;

wherein said severe disease comprises subcutaneous nodule formation or extra-articular involvement.

49. The method of claim 48, wherein said frequency of $CD4^+/CD28^{null}$ cells comprises the percent of $CD4^+$ cells that are CD28 negative.

50. The method of claim 48, wherein said reference frequency is derived from the $CD4^+/CD28^{null}$ cell frequency from a population.

51. The method of claim 50, wherein said population comprises a population of patients having a diffuse rheumatoid arthritis condition.

52. The method of claim 50, wherein said population comprises a population of patients having a follicular rheumatoid arthritis condition.

53. The method of claim 50, wherein said population comprises a population of patients having a granulomatous rheumatoid arthritis condition.

54. The method of claim 50, wherein said population comprises a population of healthy individuals.

50

55. The method of claim 50, wherein said population comprises a population of patients having subcutaneous nodules.

3

9 56. The method of claim 50, wherein said population comprises a population of patients having extra-articular involvement.

10

60. A method for determining the predisposition of a rheumatoid arthritis patient to develop severe disease, said method comprising:

a) determining the frequency of $CD4^{+}/CD28^{null}$ cells in said patient,

b) determining the presence or absence of an HLA-DRB1 allele in said patient, wherein said HLA-DRB1 allele is an HLA-DRB1 *0401 allele, an HLA-DRB1 *0404 allele, an HLA-DRB1 *0405 allele, or an HLA-DRB1 *0408 allele,

c) comparing said frequency of $CD4^{+}/CD28^{null}$ cells to a reference frequency to obtain information about said rheumatoid arthritis condition, and

d) determining if said patient is predisposed to develop severe disease based on said information and said presence or absence of said HLA-DRB1 allele;

wherein said severe disease comprises subcutaneous nodule formation or extra-articular involvement.

JXF

Attorney's Docket No. 07039-170002	Express Mail Label No.	Mailing Date July 15, 2002	*For PTO Use Only* *Do Not Mark in This Area*
Application No. 09/723,000	Filing Date November 27, 2000	Attorney/Secretary Init JXF/jaw	
Title of the Invention METHODS AND MATERIALS FOR EVALUATING RHEUMATOID ARTHRITIS			
Applicant Jorg J. Goronzy et al.			
Enclosures · Response to Notice to Comply (2 pages) · Preliminary Amendment (3 pages)			

Attorney's Docket No.: 07039-170002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jorg J. Goronzy et al.
Serial No. : 09/723,000
Filed : November 27, 2000
Title : METHODS AND MATERIALS FOR EVALUATING RHEUMATOID ARTHRITIS

Art Unit : 1648
Examiner : Stacy Brown

Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Prior to examination, please amend the application as follows:

In the claims:

Please cancel claims 58 and 59 without prejudice.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

July 15, 2002
Date of Deposit

Judy Wasilkus
Signature

Judy Wasilkus
Typed or Printed Name of Person Signing Certificate

REMARKS

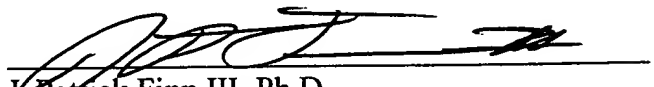
Claims 58 and 59 have been cancelled herein without prejudice.

Attached is a marked-up version of the changes being made by the current amendment.

Applicants ask that all claims be examined. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: July 15, 2002



J. Patrick Finn III, Ph.D.
Reg. No. 44,109

Fish & Richardson P.C., P.A.
60 South Sixth Street
Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

Version with markings to show changes made

In the claims:

Claims 58 and 59 have been cancelled.

Attor. 's Docket No.: 07039-170002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jorg J. Goronzy et al.
Serial No. : 09/723,000
Filed : November 27, 2000
Title : METHODS AND MATERIALS FOR EVALUATING RHEUMATOID ARTHRITIS

Art Unit : 1648
Examiner : Stacy Brown

Commissioner for Patents
Washington, D.C. 20231

RESPONSE TO NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCES

In response to the communication dated July 2, 2002 (copy enclosed), Applicants respectively submit that no sequence listing is required since (1) all sequence listing requirements were complied with as explained in Applicants' Communication mailed June 4, 2002 and (2) claims 58 and 59 have been cancelled as set forth in the Preliminary Amendment filed herewith.

Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: July 15, 2002

J. Patrick Finn III, Ph.D.
Reg. No. 44,109

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60 South Sixth Street, Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

60094690.doc

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

July 15, 2002
Date of Deposit

Judy Wasilkus
Signature

Judy Wasilkus
Typed or Printed Name of Person Signing Certificate

Application No.: 09/723,000

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Claims 58-59 require SEQ ID NO; they contain references to amino acid positions of a polypeptide

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:
For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support (SIRA)
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

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Attorney's Docket No.	Express Mail Label No.	Mailing Date	*For PTO Use Only*
07039-170002		July 15, 2002	*Do Not Mark in This Area*
Application No.	Filing Date	Attorney/Secretary Init	
09/723,000	November 27, 2000	JXF/jaw	

Title of the Invention
METHODS AND MATERIALS FOR EVALUATING RHEUMATOID ARTHRITIS

Applicant
Jorg J. Goronzy et al.

Enclosures
· Response to Notice to Comply (2 pages)
· Preliminary Amendment (3 pages)

MSE
JXF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,000	11/27/2000	Jorg J. Goronzy	07039-170002	4888

7590 07/02/2002

Mark S Ellinger PhD
Fish & Richardson PC PA
60 South Sixth Street
Suite 3300
Minneapolis, MN 55402

EXAMINER
BROWN, STACY S

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/02/2002 //

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED BY PRACTICE SYSTEMS
ACTION: Seq. Listing - IMO.
BASE: 7-2-02
DUE: 8-2-02
DEADLINE: 1-2-03
INITIALS:

Docketed By Billing Secretary
Due Date: 8/2/02
Deadline: 1/2/03
Initials: DAS 7/9/02

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	15

Please find below a communication from the EXAMINER in charge of this application

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Claims 58-59 contain references to amino acid positions 74, 70 and 71, respectively. A sequence identifier is required for examination of claims 58-59. Lacking the SEQ ID number, there is no reference for the polypeptide having an uncharged amino acid at positions 74, 70 and 71 of GLA-DRB1 allele.

APPLICANT IS GIVEN ONE EXTENDABLE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

A reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (**<http://www.uspto.gov/ebc/efs/downloads/documents.htm>**, EFS Submission User Manual - ePAVE)

2. Mailed to:
U.S. Patent and Trademark Office
Box Sequence, P.O. Box 2327
Arlington, VA 22202

3. Mailed by Federal Express, United Parcel Service or other delivery service to:
U. S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Box Sequence
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

4. Hand Carried directly to the Customer Window at:
2011 South Clark Place
Crystal Plaza Two, Lobby, Room 1B03, Box Sequence,
Arlington, Virginia 22202

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Stacy S. Brown whose telephone number is (703) 308-2361. If the examiner cannot be reached, inquiries can be directed to Supervisory Patent Examiner James Housel whose telephone number is (703) 308-4027. The fax number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stacy S. Brown
June 21, 2002

HANKYEL T. PARK, PH.D
PRIMARY EXAMINER

Application No.: 09/723,000

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Claims 58-59 require SEQ ID NO; they contain references to amino acid positions of a polypeptide

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:
For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,000	11/27/2000	Jorg J. Goronzy	07039-170002	4888

7590 04/04/2002

Mark S Ellinger PhD
Fish & Richardson PC PA
60 South Sixth Street
Suite 3300
Minneapolis, MN 55402

EXAMINER	
BROWN, STACY S	
ART UNIT	PAPER NUMBER
1648	8

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED BY PRACTICE SYSTEMS
ACTION: Seq. listing - 1 MO.
BASE: 4-4-02
DUE: 5-4-02
DEADLINE: 10-4-02
INITIALS:

Docketed By Billing Secretary
Due Date: 5/4/02
Deadline: 10/4/02
Initials: DAS 4/17/02

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	8

Please find below a communication from the EXAMINER in charge of this application

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN ONE EXTENDABLE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

A reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (**<http://www.uspto.gov/ebc/efs/downloads/documents.htm>**, EFS Submission User Manual - ePAVE)

2. Mailed to:
U.S. Patent and Trademark Office
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Arlington, VA 22202

3. Mailed by Federal Express, United Parcel Service or other delivery service to:
U. S. Patent and Trademark Office
2011 South Clark Place
Customer Window, Box Sequence
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

4. Hand Carried directly to the Customer Window at:
2011 South Clark Place
Crystal Plaza Two, Lobby, Room 1B03, Box Sequence,
Arlington, Virginia 22202

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Stacy S. Brown whose telephone number is (703) 308-2361. If the examiner cannot be reached, inquiries can be directed to Supervisory Patent Examiner James Housel whose telephone number is (703) 308-4027. The fax number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stacy S. Brown
April 2, 2002

HANKYEL T. PARK, PH.D
PRIMARY EXAMINER

Application No.: 09/723,000

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

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☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

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☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Claims 58-59 must be referenced by a SEQ ID NO.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:
For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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To Purchase PatentIn Software.....703-306-2600

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